Message

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Sent: 4/16/2021 6:00:40 PM
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Subject: First GMO Mosquitoes to Be Released In the Florida Keys

FYI – overall I would say a fair representation of the different sides of the issue, including opinions.

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First GMO Mosquitoes to Be Released In the Florida Keys

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The EPA approved Oxitec's mosquitoes for release this spring. Some scientists and locals want to halt the deployment.

Visual: Victor Moriyama / Getty Images

BY TAYLOR WHITE
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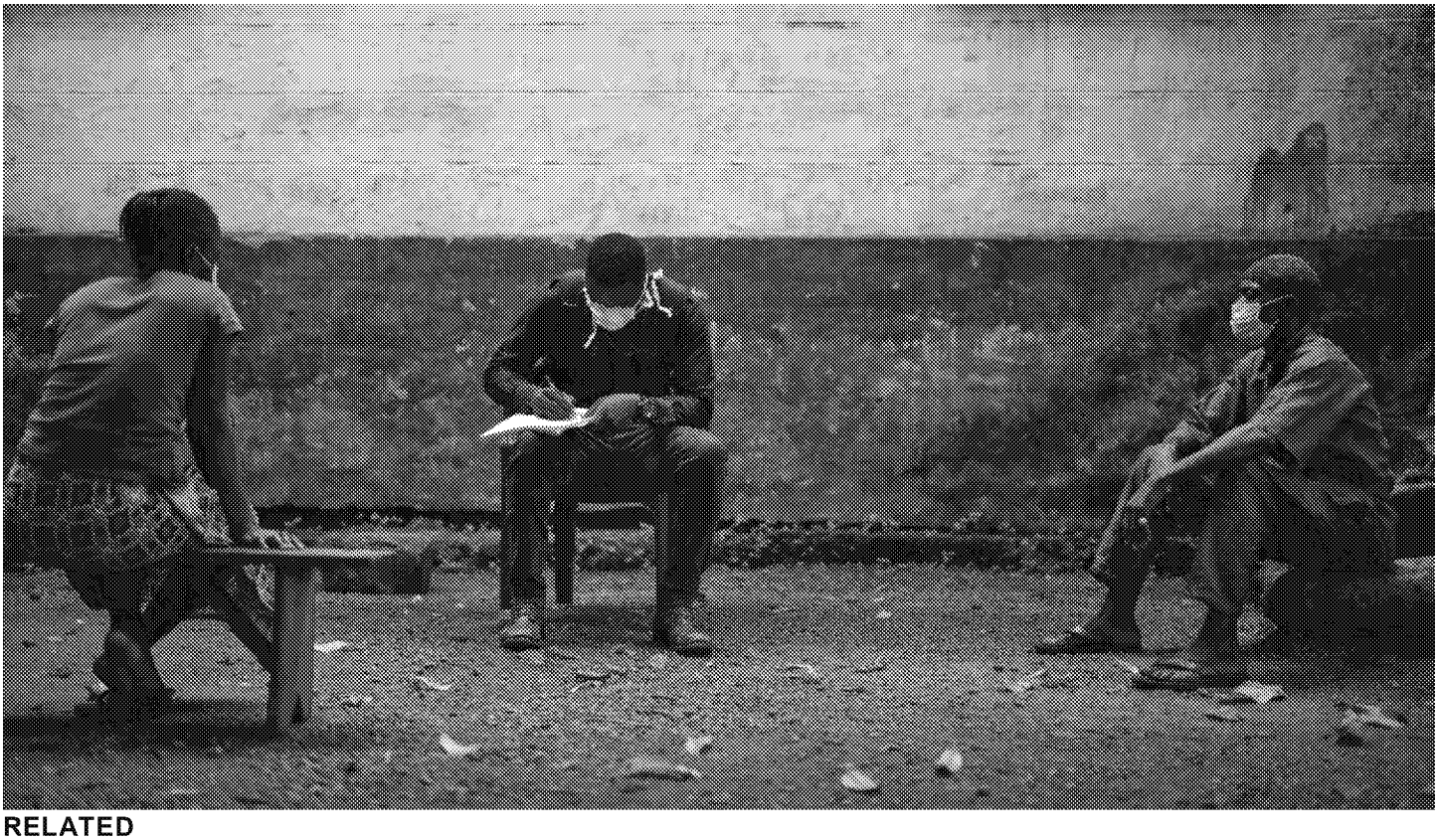
THIS SPRING, the biotechnology company Oxitec plans to release genetically modified (GM) mosquitoes in the Florida Keys. Oxitec says its technology will combat dengue fever, a potentially life-threatening disease, and other mosquito-borne viruses — such as Zika — mainly transmitted by the *Aedes aegypti* mosquito.

While there have been more than 7,300 dengue cases reported in the United States between 2010 and 2020, a majority are contracted in Asia and the Caribbean, according to the U.S. Centers for Disease Control and Prevention. In Florida, however, there were 41 travel-related cases in 2020, compared with 71 cases that were transmitted locally.



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Native mosquitoes in Florida are increasingly resistant to the most common form of control — insecticide — and scientists say they need new and better techniques to control the insects and the diseases they carry. "There aren't any other tools that we have. Mosquito nets don't work. Vaccines are under development but need to be fully efficacious," says Michael Bonsall, a mathematical biologist at the University of Oxford, who is not affiliated with Oxitec but has collaborated with the company in the past, and who worked with the World Health Organization to produce a GM mosquito-testing framework.

Bonsall and other scientists think a combination of approaches is essential to reducing the burden of diseases — and that, maybe, newer ideas like GM mosquitoes should be added to the mix. Oxitec's mosquitoes, for instance, are genetically altered to pass what the company calls "self-limiting" genes to their offspring; when released GM males breed with wild female mosquitoes, the resulting generation does not survive into adulthood, reducing the overall population.

But Oxitec has been proposing to experimentally release GM mosquitos in the Keys since 2011, and the plan has long been met with suspicion among locals and debate among scientists. Some locals say they fear being guinea pigs. Critics say they are concerned about the possible effects GM mosquitoes could have on human health and the environment. In 2012, the Key West City Commission objected to Oxitec's plan; in a non-binding referendum four years later, residents of Key Haven — where the mosquitoes would have been released — rejected it, while residents in the surrounding county voted in support of the release. With the decision left up to the Florida Keys Mosquito Control District, officials approved the trial to be conducted elsewhere in the Keys.

According to Oxitec, the release was delayed due to a transfer of jurisdiction over the project from the U.S. Food and Drug Administration to the Environmental Protection Agency.

The company reapplied for approval to release a new version of the mosquitoes, called OX5034, in the Keys. In May, the EPA granted a two-year experimental use permit, which the agency can cancel at any time. State and local sign-off soon followed — finally giving the project the greenlight.

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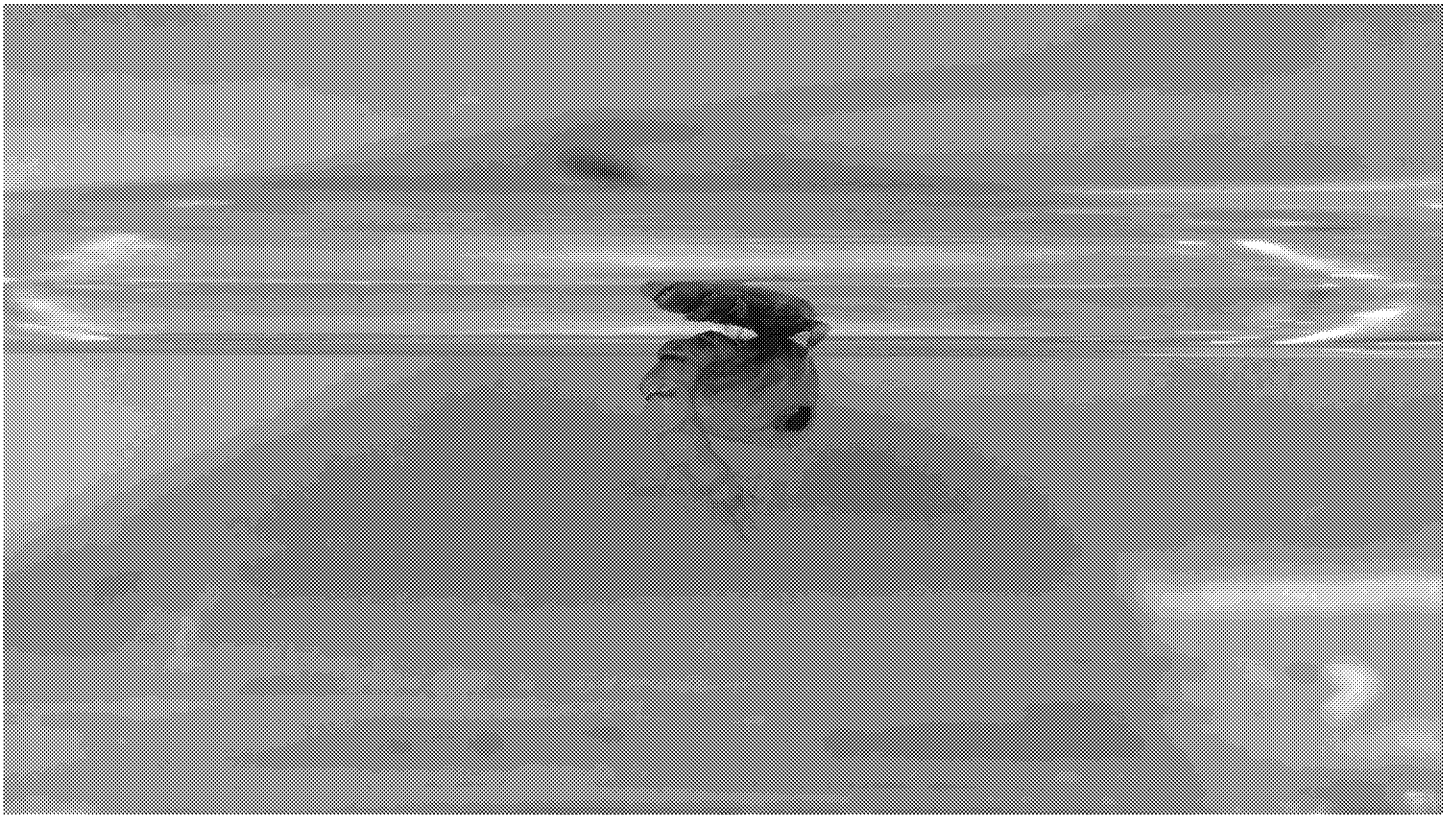
Oxitec's OX5034 mosquitoes are the first GM mosquitoes approved for release in the U.S. The company has already conducted a trial with the OX5034 mosquitoes in Brazil and released more than a billion of a previous version, called OX513A, there and in other locations over the years — including the Cayman Islands. The company says it is confident in the effectiveness and safety of the technology.

But some scientists want to hit pause on Oxitec's Florida trial, to find what they say is a fairer process in deciding to release the mosquitoes. Others want to see clearer proof that this technology is even necessary, claiming that the company has only released its most positive data with the public and has kept other key data, including whether the mosquitoes curb disease transmission, private. And if the release actually launches as planned, some Keys residents say they aim to interfere.

Critics also say that Oxitec failed to engage with local communities in Florida and get their consent to release the mosquitoes. "What's the most upsetting is that the very people that are going to be most impacted, both by the benefits or the risks of such a decision, have like the smallest voice in how these choices are made. I think that's a really big issue," says Natalie Kofler, a molecular biologist and bioethicist who founded Editing Nature, a platform that advocates "for inclusive decision-making processes to steer" the use of genetic technology. "If Oxitec doesn't do this right," she adds, "we could have huge impact on delaying the use of other beneficial technologies like that in the future."

OXITEC'S OX5034 MOSQUITOES are programmed to combat the transmission of mosquito-borne illnesses by suppressing local *Aedes aegypti* populations. Oxitec — which is U.S.-owned and based in the United Kingdom — describes their mosquitoes as "friendly" because they will only release males, which, unlike females, do not bite humans or transmit disease.



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At Oxitec's laboratory in the U.K., the company genetically engineers the mosquitoes, giving the insects the "self-limiting" gene that makes the females dependent on the antibiotic tetracycline. Without the drug, they will die. Eggs from these genetically-altered mosquitoes — which will hatch both male and female insects — will be shipped to the Keys. Mosquitoes require water to mature from an egg to an adult; when Oxitec's team adds water to the boxes the mosquitoes will be deployed in, both GM males and GM females will hatch. With no tetracycline present in the box, the GM females are expected to die in early larval stages.

The male mosquitoes will survive and carry the gene. When they leave the boxes, the insects will, hypothetically, fly away to mate with wild females to pass the gene to the next wild generation, according to Nathan Rose, head of regulatory affairs at Oxitec. Kevin Gorman, the company's chief development officer, says the local female mosquito population will be increasingly reduced — which will also reduce the number of wild male mosquitoes in the treatment areas.

Gorman emphasized to Undark that the EPA and other regulators found no risk in using tetracycline in breeding their genetically-altered mosquitoes. But some scientists think the presence of this antibiotic in the environment does pose a risk. According to Jennifer Kuzma, co-founder and co-director of the Genetic Engineering and Society Center at North Carolina State University, tetracyline is commonly used in Florida to prevent bacterial diseases in agriculture — particularly in citrus groves — and to treat bacteria in sewage plants. The use of the antibiotic for these purposes may mean that it will remain in the environment, especially in water where the mosquitoes breed, which could allow Oxitec's female mosquitoes to survive. While the company does not plan to release the mosquitos near areas where the antibiotic is used, Kuzma says the EPA's risk assessment did not include testing of any standing water for tetracycline — something, she adds, "would have been easy enough to do for good due diligence."

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Skeptics of Oxitec's GM mosquitoes include local residents, physicians, scientists, and environmental activists. Many of these opponents say they aren't anti-GMO, but disagree with how the approval process has been handled. One group has even kept a running list of what it sees as Oxitec's wrongdoings since it first began experimental releases. The list includes Oxitec's lack of disease monitoring in the countries where it has released mosquitoes; the unknown price of its technology; and complaints that the company has overstated the success of some of it its trials.

"I cannot trust this company. I cannot trust this technology," says Mara Daly, a resident of Key Largo who says she's been following Oxitec's plans for nine years.

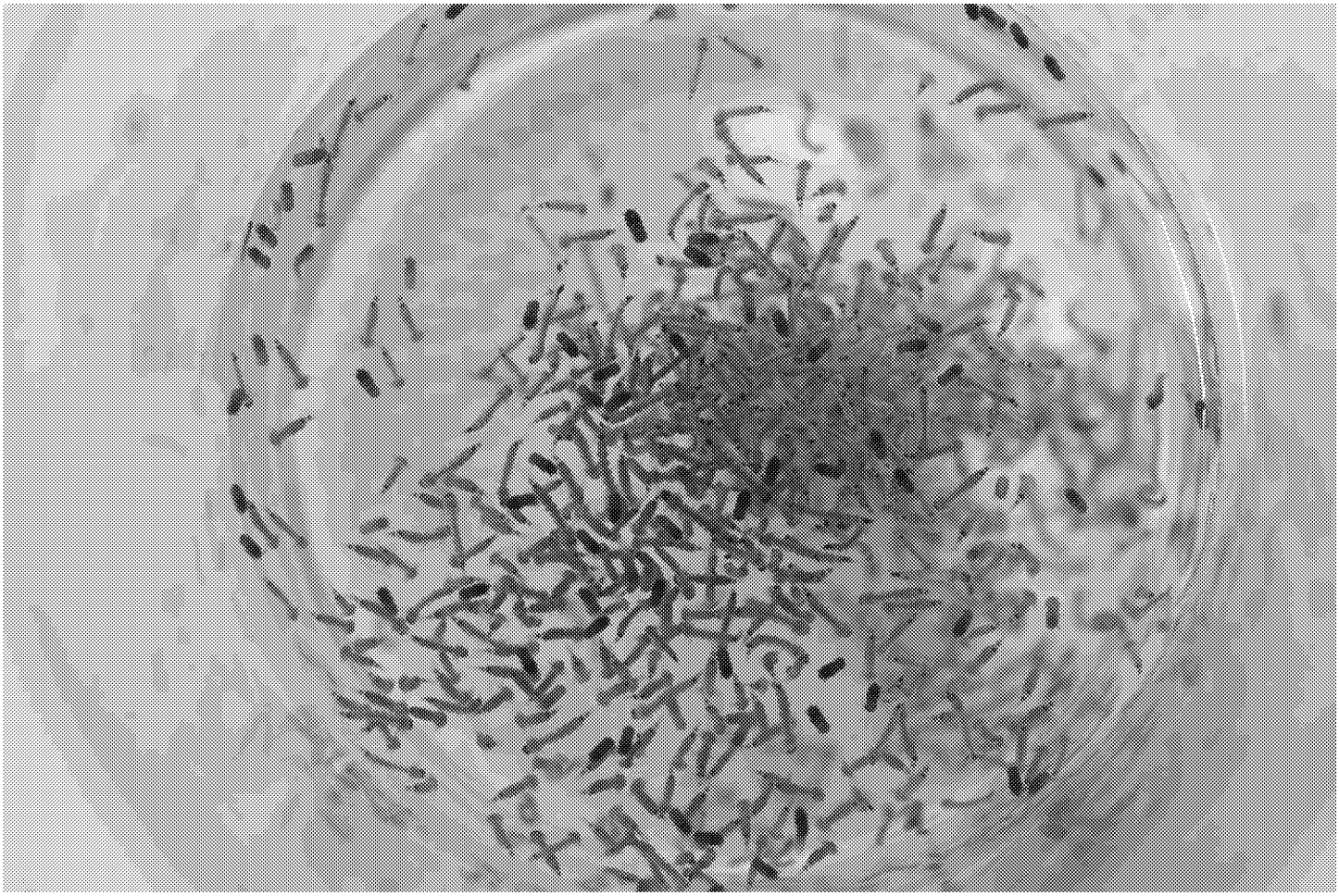
"This is not a traditional pesticide," she adds. " This is not a chemical that you can trace. This is something completely different, new emerging technology and we need better regulation."

Phil Goodman, chairman of the Florida Keys Mosquito Control District (FKMCD), an independently-elected commission carrying out mosquito control within Monroe County, says that many of those who discredit Oxitec's evidence do not understand the technology. "They're fearmongering," he says.

"They have very little credibility here in the Florida Keys as far as I'm concerned," he adds.

But people like Daly and Barry Wray, executive director of the Florida Keys Environmental Coalition, disagree. "We want to know it's safe," says Wray, who notes that his group more generally supports GM technology. "We don't have another Florida Keys ecosystem. We don't have another Florida Keys community. We have this one."

Daly, Wray, and others point to what they perceive as the FKMCD's disrespect for public opinion. They argue that the community wasn't given a chance to consent before the EPA approval. There was a 30-day public forum in September 2019 about Oxitec's technology application, with 31,174 comments opposing release and 56 in support. A statement emailed to Undark by Melissa Sullivan, an EPA spokesperson, noted that the agency considered these comments during the review, but critics think it happened too quickly to be of real use.



In the early larval stages, Oxitec's female mosquitoes are expected to die because they have been genetically modified to depend on an antibiotic. *Visual: Nelson Almeida / AFP via Getty Images*

In Brazil, Oxitec mosquitoes are raised in a lab and then released in areas with a high concentration of *Aedes aegypti* mosquitoes. *Visual: Nelson Almeida / AFP via Getty Images*

Once released, male GM mosquitoes mate with wild females to pass the gene on to the next generation, reducing the local female population — and eventually the number of wild male mosquitoes. Oxitec has already

released more than a billion of a previous version of GM mosquitoes, OX513A, in Brazil and other locations. *Visual: Victor Moriyama / Getty Images*

In June, Kofler and Kuzma wrote an opinion piece in The Boston Globe about the EPA approval, critiquing the agency's regulatory system and calling for a better process for evaluating new biotechnologies. The researchers expressed concern that "the EPA did not convene an independent, external scientific advisory panel to review" Oxitec's claims about its mosquito strategy and that the agency only publicly released its risk assessment after approving the technology. The "American public," Kofler and Kuzma wrote, "needs to be assured that these decisions are made free of conflicts of interest." The statement from the EPA's Sullivan noted that the agency "conducted an extensive risk assessment based on the best available science."

Some critics also wanted there to be more public engagement. Kofler and Kuzma say they offered to provide their expertise, along with other outside experts, to the mosquito control district to allow more discussion about the GM mosquitoes with the Keys community. But Kofler says the district wasn't responsive. Oxitec itself launched webinars about their new product, but not until after the EPA approval. "Here we are, like in the final hour, having these conversations that needed to be happening a year ago," says Kofler.

Without public trust and enthusiasm, it doesn't matter whether Oxitec's mosquito technique works, says Guy Reeves, a genetic researcher at the Max Planck Institute for Evolutionary Biology in Germany, who stresses that he doesn't think the company's approach is unsafe. "If the population in Florida Keys becomes so sensitized to this issue — that they can no longer cooperate with each other — that's good for the mosquitoes, not good for the people," he adds.

Based on their first generation mosquito OX513A, Oxitec says it has shown that the approach reduces a targeted mosquito population in trials in both Brazil and the Cayman Islands. But there's no evidence that this new OX5034 mosquito release will actually be worth it for mosquito suppression, says Reeves. Oxitec also hasn't explained how their new mosquito will directly curb human diseases, such as dengue. Reducing disease transmission and burden should be measures of efficacy for this technology, says Kofler.

According to Gorman, independent disease suppression data has only been collected by municipalities in Brazil because that's where most of the company's trials have been released in larger scales. These municipalities have shown that Oxitec mosquitoes have reduced dengue cases in areas of release, Gorman says. In order for Oxitec to collect additional data, he adds, the company needs to release and test large areas over sustained periods of time. Gorman maintains that the company is not required to report formal health impact studies.

Reeves adds that Oxitec also hasn't explained what resources are needed to sustain this product, how long it could take to be effective, or the cost. When asked about the cost of the Florida Keys project, Oxitec responded to Undark by email: "Oxitec is a pre-commercial, pre-profit company. We will not profit from this pilot project in Florida. We are paying for it ourselves."

OXITEC HAS RELEASED more than a billion of their OX513A mosquitoes over the past 10 years. According to independent scientists, some of those experiments did not go well.

For example, researchers at Yale University and collaborators from Brazil analyzed Oxitec's 2015 release of OX513A in Brazil. The scientists confirmed that some offspring of the genetically modified mosquitoes — which were supposed to die and not pass new genes to the wild population — survived

to adulthood and mated with their native counterparts. Between 10 and 60 percent of the native mosquitoes contained genes from Oxitec, according to the Yale study, which published in Nature in 2019. The paper's authors concluded they do not know what impacts these mixed mosquitoes have on disease control or transmission, but added that their findings underscore the importance of monitoring the genetics of the insects.

Oxitec disagreed with the findings and responded on the journal's website. Oxitec told Gizmodo that Yale's study includes "numerous false, speculative, and unsubstantiated claims and statements about Oxitec's mosquito technology." And when Kofler and three other scientists wrote about Oxitec's Brazil trial in The Conversation, Oxitec pushed to have the article retracted, says Kofler.

"Here we are, like in the final hour, having these conversations that needed to be happening a year ago," says Kofler.

For this coming release, some Key Largo locals are willing to act on their anger. Daly, for instance, says that if the mosquitoes are deployed in her neighborhood, she'll try to put insecticide in any box she finds or send it to an expert to test — even if it means getting in trouble with the federal authorities. "I already have my arresting officer and she said she's gonna clean her handcuffs for me," she says. "I don't care."

Ideally, Daly says, it won't have to come to that. She and other locals hope to stop Oxitec before the latest mosquitos are delivered. Daly says she has been busy organizing protests — like one that happened recently in Key Largo — and giving out yard signs to residents who don't want their property used in the trial. "Locals are pissed off. So I have been busy getting the press to cover the local opposition," Daly wrote in an email to Undark.

"The first flying insect or animal that can actually use our human blood for a friggin trial for a product to come to market without my consent," Daly says.

"That's my blood," she adds. "That's my son's blood. That's my dog's blood."

Taylor White is a freelance journalist based in Cape Cod, MA and a graduate of the Science, Health & Environmental Reporting Program at the NYU school of journalism. Her work has appeared in NOVA GBH, Dana-Farber Cancer Institute, the American Association for the Advancement of Science, GenomeWeb, Spectrum, and Science Vs.

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